

AMENDMENTS TO THE CLAIMS

Please amend claims as shown below.

1. (Currently Amended) An integrated photosensitizing assembly for treating tissue, comprising: (a) a quantity of photosensitizing material; (b) a carrier which is combined with the photosensitizing material such that the photosensitizing material is substantially uniformly dissolved or suspended therein; and (c) a substrate to which the carrier-photosensitizing material combination is applied including a tissue contacting layer having a target portion and a fluid transporting layer adjacent said tissue contacting layer and aligned with the target portion, said target portion capable of receiving electromagnetic energy and converting it into thermal energy for tissue poration.
2. (Currently Amended) The photosensitizing assembly of claim 1, and further comprising a layer of priming material between the substrate and the carrier.
3. (Currently Amended) The ~~photosensitizing~~ assembly of claim 1, wherein the photosensitizing material is a dye or a pigment.
4. (Currently Amended) The photosensitizing assembly of claim 1, wherein the carrier is one of a solid polymer, adhesive, gel and ink.
5. (Currently Amended) An The assembly of integrated poration, harvesting and analysis device comprising the photosensitizing assembly of claim 1, wherein said target portion is capable of converting laser energy into thermal energy. the device comprises: (a) a tissue contacting layer having a target portion comprised of the

~~photosensitizing assembly; and (b) fluid transporting layer adjacent the tissue contacting layer and aligned with the target portion.~~

6. (Currently Amended) ~~The device~~ The assembly of claim 5, ~~and further comprising a meter interface layer overlying the fluid transporting layer~~ further comprising a detection layer having an electro-chemical biosensor which is responsive to the fluids received from the tissue.
7. (Currently Amended) ~~An~~ photosensitizing assembly for treating porating tissue, comprising: (a) a quantity of photosensitizing material, said material capable of converting laser energy into thermal energy; and (b) a film material containing a substantially uniform suspension of the photosensitizing material comprising a target area for receiving laser energy and porating tissue by heating.
8. (Original) The photosensitizing assembly of claim 7, and wherein the film material is made of one of polyesters, polyimides, polyethylenes, polypropylenes, acrylics, cellulose and derivatives thereof.
9. (Original) The photosensitizing assembly of claim 8, wherein the photosensitizing material is a dye or pigment.
10. (Original) An integrated poration, harvesting, and analysis device comprising the photosensitizing assembly of claim 7, wherein the device comprises: (a) a tissue-

contacting layer having a target portion comprised of the photosensitizing assembly; and (b) fluid-transporting layer adjacent the tissue-contacting layer and aligned with the target portion.

11. (Original) The device of claim 10, and further comprising a meter-interface layer adjacent the fluid-transporting layer.
12. (Currently Amended) A method ~~for treating~~ of porating tissue comprising the steps of: (a) applying a photosensitizing assembly including a quantity of photosensitizing material to the tissue; and (b) subjecting said photosensitizing assembly to electromagnetic radiation to cause thermal ablation of the tissue.
13. (Original) The method of claim 12, wherein the step of applying comprises applying a substrate to which is applied a carrier in which the quantity of photosensitizing material is substantially uniformly dissolved or suspended.
14. (Original) The method of claim 13, wherein the step of applying comprises adhering the substrate to the tissue.
15. (Original) The method of claim 12, wherein the step of applying comprises applying a film incorporating a substantially uniform suspension of the photosensitizing material.

16. (Original) The method of claim 12, wherein the electromagnetic radiation is in a wavelength range from about 10 nm to about 50,000 nm.
17. (Original) The method of claim 12, wherein said step of subjecting comprises emitting electromagnetic radiation from a polychromatic light source.
18. (Original) The method of claim 12, wherein said step of subjecting comprises emitting electromagnetic radiation from a laser.
19. (Original) The method of claim 12, and further comprising the step of withdrawing body fluids from an opening created in said tissue.
20. (Original) The method of claim 19, and further comprising the step of determining the concentration of at least one analyte in the body fluids.
21. (Original) The method of claim 20, wherein the step of determining comprises determining the concentration of glucose.
22. (Currently Amended) The method of claim 12, and further comprising the step of introducing a permeant into an said opening created by said ablation.
23. (Currently Amended) An integrated poration, harvesting and analysis device, for porating tissue, comprising: (a) a tissue-contacting layer, a heat generating having a

probe in thermal communication with the ~~thereon suitable for conducting heat to a~~
surface of the ~~of a~~ tissue to form at least one opening therein; and (b) a detecting
layer in fluid communication with the at least one opening formed in the surface of the
tissue, the detecting layer being responsive to a biological fluid collected from the
tissue to provide an indication of a characteristic of the biological fluid.

24. (Currently Amended) The device of claim 23, wherein the probe is capable of being
heated such that the temperature of tissue-bound water and other vaporizable
substances in a selected area of the surface of the tissue is elevated above the
vaporization point of water and other vaporizable substances thereby removing the
surface of the tissue in said selected area

25. (Original) The device of claim 24, wherein the probe forms a micropore in the surface
of the tissue approximately 1-1000 .mu.m in diameter.

26. (Original) The device of claim 23, wherein the probe comprises at least one
electrically heated probe

27. (Original) The device of claim 26, and further comprising at least two conductors
embedded in the tissue-contacting layer and at least one electrically heatable
element connected to the conductors for supplying electric current to the at least one
electrically heatable element.

28. (Original) The device of claim 23, wherein the probe comprises a target portion on the tissue-contacting layer which is responsive to optical energy so as to heat up and conduct heat to the tissue.

29. (Original) The device of claim 28, wherein the target portion comprises a quantity of photosensitizing material, and a carrier which is combined with the photosensitizing material such that the photosensitizing material is substantially uniformly dissolved or suspended therein, wherein the tissue-contacting layer serves as a substrate for the carrier-photosensitizing material combination.

30. (Original) The device of claim 28, wherein the tissue-contacting layer comprises a film material, and wherein the target portion comprises a substantially uniform suspension of photosensitizing material in the film material.

31. (Original) The device of claim 23, wherein the detecting layer comprises an electrochemical biosensor which is responsive to a level of glucose in interstitial fluid.

32. (Original) The device of claim 31, and further comprising a meter-interface layer comprising electrical contacts connected to the electrodes of the electrochemical biosensor, and which electrical contacts are suitable for connection to a meter.

33. (Original) The device of claim 23, wherein the detecting layer comprises a colorimetric sensor which provides an indication of glucose level in interstitial fluid.

34.(Original) The device of claim 33, and further comprising a meter-interface layer having a portion thereof which is transparent to optical energy.

35.(Original) The device of claim 23, and further comprising a mechanical element suitable for pressing the device onto a surface of the tissue to cause the surface of the tissue to bulge into an opening of the device proximate the probe.

36.(Original) The device of claim 23, and further comprising sealing means for pneumatically sealing the device to the surface of the tissue and forming a sealed chamber above the device; and means coupled to the sealing means for supplying negative pressure to the sealed chamber.

37.(Original) The system of claim 36, and further comprising a sealed electrical connection to the detecting layer and/or probe via the sealing means.

38. (Original) The device of claim 23, and further defining a fluid management chamber in a region of the device between the tissue-contacting layer and the detecting layer, wherein surfaces in the fluid management chamber are treated with a chemical substance so as to facilitate the flow of biological fluid to the detecting layer

39.(Currently Amended) An integrated poration, harvesting and analysis device, comprising: (a) a tissue-contacting layer having a probe thereon suitable for

conducting heat to a surface of a tissue to form at least one opening therein; and (b) a detecting layer in fluid communication with the at least one opening formed in the surface of the tissue, the detecting layer being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid and The device of claim 38, wherein surface portions of the tissue-contacting layer are coated with hydrophobic substances

40. (Currently Amended) An integrated poration, harvesting and analysis device, comprising: (a) a tissue-contacting layer having a probe thereon suitable for conducting heat to a surface of a tissue to form at least one opening therein; and (b) a detecting layer in fluid communication with the at least one opening formed in the surface of the tissue, the detecting layer being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid and The device of claim 23, and further comprising a sense electrode coupled to the detecting layer to facilitate determination that the detecting layer is sufficiently wetted with biological fluid.

41. (Original) The device of claim 23, and further comprising a fluid-transporting layer between the tissue-contacting layer and the detecting, and in fluid communication with the detecting layer.

42. (Original) The device of claim 41, wherein fluid-transporting layer comprises a mesh material capable of wicking biological fluid.

43. (Original) The device of claim 41, wherein the fluid-transporting layer is treated with a chemical substance to enhance wicking capabilities of interstitial fluid.

44. (Original) The device of claim 41, wherein the fluid-transporting layer is treated with a surfactant.

45. (Original) The device of claim 23, and further comprising an overcoat layer which overlies the tissue-contacting layer

46. (Original) The device of claim 23, and further comprising means for coupling sonic energy through the device to the tissue.

47. (Original) The device of claim 46, and further comprising control means for controlling parameters of the sonic energy so that the sonic energy is adjusted to optimize each stage of a microporation, harvesting and analysis process.

48. (Original) A glucose monitoring system comprising: a poration/assay carriage supporting a poration head comprising at least one electrically heated probe, and an assay strip; a vacuum chamber mechanism for engaging a tissue surface and applying a vacuum in a chamber in which the poration/assay carriage is supported; means for supplying electrical current to the poration head so as to heat the electrically heated probe to form at least one micropore in the surface of the tissue;

means for moving the poration/assay carriage with respect to the surface of the tissue so as to contact the assay strip with a bolus of biological fluid collected from the surface of the tissue; and means for interfacing with the assay strip to obtain a measurement of a characteristic of the biological fluid.

49.(Original) The system of claim 48, wherein the poration/assay carriage comprises a poration head having a plurality of electrically heated probes thereon.

50.(Original) A assay cartridge comprising: a plurality of assay elements, wherein each assay element comprises: a heated probe surface suitable for forming micropores when placed in contact with tissue; a fluid accumulation area adjacent the heated probe surface suitable for accumulating biological fluid on the surface of the tissue; and an assay area suitable for receiving a bolus of biological fluid from the fluid accumulation area to enable measurement of a characteristic of the biological fluid.

51.(Currently Amended) A glucose monitoring system comprising: a poration/assay carriage supporting a poration head comprising at least one electrically heated probe, and a assay strip; a vacuum chamber mechanism for engaging a tissue surface and applying a vacuum in a chamber in which the poration/assay carriage is supported; means for supplying electrical current to the poration head so as to heat the electrically heated probe to form at least one micropore in the surface of the tissue; means for moving the poration/assay carriage with respect to the surface of the tissue so as to contact the assay strip with a bolus of biological fluid collected from

the surface of the tissue; and means for interfacing with the assay strip to obtain a measurement of a characteristic of the biological fluid and further including a plurality of assay elements, wherein each assay element comprises: a heated probe surface suitable for forming micropores when placed in contact with tissue; a fluid accumulation area adjacent the heated probe surface suitable for accumulating biological fluid on the surface of the tissue; and an assay area suitable for receiving a bolus of biological fluid from the fluid accumulation area to enable measurement of a characteristic of the biological fluid and A system comprising the assay cartridge of claim 50, and further comprising further including means for rotating the cartridge so as to contact each of the assay element during the microporation, harvesting and analysis process.

52. (New) An integrated poration, harvesting and analysis device, comprising: (a) a tissue-contacting layer having a hole therethrough to permit a porator to create at least one opening in the tissue; and (b) a detecting layer in fluid communication with the at least one opening formed in the surface of the tissue, the detecting layer being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid.